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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,863	07/13/2005	Youe-Kong Shue	5176-14PUS	4452

27799 7590 05/13/2008

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EXAMINER
MARX, IRENE

ART UNIT	PAPER NUMBER
1651	

MAIL DATE	DELIVERY MODE
05/13/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/520,863	SHUE ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed 3/3/08 is acknowledged. Claims 28-40 are being considered on the merits.

Claim 27 is indicated as "cancelled". Yet no claim 27 was present in the record.

The rejection under 35 U.S.C 112, first paragraph regarding deposit is withdrawn in view of applicant's evidence.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 28-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hochlowski *et al.* taken with McAlpine *et al.,* Coronelli *et al.* (U.S. Patent No. 3978211), Waters *et al.* (U.S. Patent No. 4,632,902), Hoefle *et al.* (U.S. Patent No. 7,067,544) and Demain *et al.*

The claims are directed to a process of producing tiacumicins by culturing a microorganism wherein there is an absorbent "capable of absorbing tiacumicin in the culture medium".

Hochlowski *et al.* disclose a process of producing tiacumicins by culturing a microorganism with a yield of tiacumicins greater that about 50 mg/l under conventional culturing conditions. See, e.g., page 575, penultimate paragraph, line 9.

In addition, the production of various tiacumicin compound is disclosed by McAlpine *et al.* who teaches the production of tiacumicins with strain *Dactylosporangium aurantiacum subspecies hamdenensis* NRRL 18085 (See, e.g., Examples) and by Coronelli *et al.* (U.S. Patent No. 3978211) who teaches the production of lipiarmycins with *A. deccanensis.*

The invention as claimed differs from the references in the use of an absorbent or specifically, adsorbent resin in the culture medium. However, each of Hoefle *et al.* and Waters *et al.* adequately demonstrates that it is old and well known in the art the add adsorbent resins, such as XAD-16 to culture media, for example, to isolate antibiotics produced by the strain or to isolate any antimicrobials present and thus prevent growth inhibition of the microorganisms cultured. See, e.g., Hoefle *et al.*, Example 3 and Waters *et al.*, bridging paragraph between col. 3 and 4 and col. 5. In addition McAlpine recognizes the benefit of using silica gel in conjunction with tiacumicin (See, e.g., col. 7, lines 30-45) for purification purposes at least.

The process conditions discussed in the references appear to be substantially the same as claimed. However, even if they are not, the adjustment of process conditions, such as the sources of nutrients for the microorganism and the use of various adsorbents, including reverse silica gel, for optimization purposes identified as result-effective variables cited in the references would have been prima facie obvious to a person having ordinary skill in the art, since such adjustment is at the essence of biotechnical engineering. See, e.g., Demain *et al.* pages 123-126.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the process of Hochlowski *et al.* of producing tiacumicins by adding an absorbent or an adsorbent resin, including silica gel, as well as adjusting the various ingredients of the culture medium, as suggested by the teachings of McAlpine, Hoefle *et al.,* Waters *et al.* and Demain *et al.* for the expected benefit of maximizing the production of tiacumicin and of tiacumicin B, in particular, for treatment of infections with *Clostridium difficile,* for example.

Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

Response to Arguments

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Applicant's arguments of unexpected results pertain to "absorbent resins" in general and not to any absorbent, for example, as in claims 28-30. In addition, it is unclear that the profile of fermentation product necessarily results in greater production of Tiacumicin B as alleged using

any strain or any adsorbent resin. It is apparent that specific conditions and a specific strain are required to achieve the touted results. See, Specification, Examples.

The scope of the showing must be commensurate with the scope of claims to consider evidence probative of unexpected results, for example. In re Dill, 202 USPQ 805 (CCPA, 1979), In re Lindner 173 USPQ 356 (CCPA 1972), In re Hyson, 172 USPQ 399 (CCPA 1972), In re Boesch, 205 USPQ 215, (CCPA 1980), In re Grasselli, 218 USPQ 769 (Fed. Cir. 1983), In re Clemens, 206 USPQ 289 (CCPA 1980). It should be clear that the probative value of the data is not commensurate in scope with the degree of protection sought by the claim.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300 .

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Irene Marx/
Primary Examiner
Art Unit 1651